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Application Number	10/829,468
Filing Date	4/21/2004
First Named Inventor	Max R. Motyka
Art Unit	1616
Examiner Name	Ernst V. Arnold
Attorney Docket Number	00015-22305

ENCLOSURES *(Check all that apply)*

- ☐ Fee Transmittal Form
  - ☐ Fee Attached
- ☐ Amendment/Reply
  - ☐ After Final
  - ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request
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- ☐ Reply to Missing Parts/ Incomplete Application
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SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	Thorpe North & Western, LLP		
Signature			
Printed name	Gary P. Oakeson		
Date	06/06/2008	Reg. No.	44266

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Signature	Brenda Wiseman		
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPELLANT:	Max R. Motyka
SERIAL NO.:	10/829,468
FILING DATE:	04/21/2004
CONF. NO.:	6421
FOR:	NON-GMO METAL AMINO ACID CHELATES AND NON-GMO METAL AMINO ACID CHELATE-CONTAINING COMPOSITIONS
ART UNIT:	1616
EXAMINER:	Ernst V. Arnold
DOCKET NO.:	00015-22305

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APPELLANTS' APPEAL BRIEF UNDER 37 C.F.R. § 41.37

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450
Mail Stop Appeal Brief – Patents

Sir:

Appellants submit this Appeal Brief in connection with their appeal from the final rejection of the Patent Office, mailed January 24, 2008, in the above-identified application. A Notice of Appeal was filed on May 19, 2008, which was received by the Board of Appeals on May 21, 2008.

TABLE OF CONTENTS

I. REAL PARTY IN INTEREST

The real party in interest of this application is Albion International, Inc., 101 North Main, Clearfield, Utah, 84015.

II. RELATED APPEALS AND INTERFERENCES

Appellants and Appellants' legal representatives know of no other appeals or interferences that will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

III. STATUS OF CLAIMS

Claims 34-53 remain pending and have been rejected. Claims 1-33 have been canceled. The claims on appeal in this application are claims 34-53.

IV. STATUS OF AMENDMENTS

An amendment to claims 1-3, 5-10, 13-28, and 30-33 was submitted by Appellants on March 24, 2008 after the Final Office Action mailed on January 24, 2008. The amendment was entered by the Examiner canceling claims 1-3, 5-10, 13-28, and 30-33.

V. SUMMARY OF CLAIMED SUBJECT MATTER

34. (original) A method of preparing a non-GMO metal amino acid chelate (page 5, lines 22-23), comprising:

a) selecting an amino acid source determined to be non-GMO (page 5, lines 23-24);

b) selecting a metal source determined to be non-GMO (page 5, line 24)and

c) chelating an amino acid of the amino acid source to a metal of the metal source, thereby forming a non-GMO metal amino acid chelate (page 4, lines 24-26).

43. (original) A method of administering a metal amino acid chelate (page 5, lines 27-28), comprising:

a) formulating a non-GMO metal amino acid chelate (page 5, line 28) by:

i) selecting an amino acid source determined to be non-GMO (page 6, lines 1-2),

ii) selecting a metal source determined to be non-GMO (page 6, line 2), and

iii) chelating an amino acid of the amino acid source to a metal of the metal source, thereby forming the non-GMO metal amino acid chelate (page 6, lines 2-4); and

b) administering the non-GMO metal amino acid chelate to the subject (page 5, line 29).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The issues presented for review are:

a. whether claims 34-36, 41-45, and 50-53 are unpatentable under 35 U.S.C. § 102(b) as being anticipated by U.S. Pat. No. 5,504,055 (hereinafter "Hsu");

b. whether claims 34-36, 41-45, and 52-53 are unpatentable under 35 U.S.C. § 102(b) as being anticipated by U.S. Pat. No. 6,426,424 (hereinafter "Ashmead '424");

c. whether claims 43-45, 50-51 and 53 are unpatentable under 35 U.S.C. § 102(b) as being anticipated by U.S. Pat. No. 4,725,427 (hereinafter "Ashmead '427"); and

d. whether claims 34, 37-40, 43 and 46-49 are unpatentable under 35 U.S.C. § 103(a) as being obvious over Hsu in view of an academic article entitled "Production and Utilization of Amino Acids" published in Angewandte Chemie International Edition authored by Yoshiharu Izumi, Ichiro Chibata, and Tamio Itoh (Angew. Chem. Int. Ed. Engl. 17, 176-183) (hereinafter "Izumi").

VII. ARGUMENT

A. Appellants' invention

Appellants' invention provides methods of preparing and administering a non-GMO metal amino acid chelate, including selecting an amino acid source determined to be non-GMO; selecting a metal source determined to be non-GMO; and chelating an amino acid of the amino acid source to a metal of the metal source, thereby forming a non-GMO metal amino acid chelate.

B. The Asserted References

1. The Hsu Reference

Hsu teaches a water soluble metal amino acid chelate prepared by adding a metal salt to deaerated water, mixing the salt solution with a mixture of an amino acid and an organic acid and adjusting the pH of the resulting composition to a range of from about 4.5 to about 8.5 to produce a clear solution. See Abstract. Notably, Hsu never discusses or discloses non-GMO metal amino acid chelates.

2. The Ashmead '424 Reference

Ashmead '424 teaches a method of preparing amino acid chelates and complexes by blending hydrated metal sulfate salts, amino acid ligands, and reaction modifiers; confining the particulate blend in an enclosed environment; and applying heat to the particulate blend in the enclosed environment causing the waters of hydration of the metal sulfate salt to be released. See Abstract. Notably, Ashmead '424 never discusses or discloses non-GMO metal amino acid chelates.

3. The Ashmead '427 Reference

Ashmead '427 discloses a flavored, effervescent, water-soluble, compositions containing water-soluble and oil-soluble vitamins and amino acid chelated minerals in bioavailable form. See Abstract. Notably, Ashmead '427 never discusses or discloses non-GMO metal amino acid chelates.

4. The Izumi Reference

Izumi teaches that amino acids can be produced by extraction from protein hydrolyzates, by fermentation with the aid of microorganisms, by enzymatic processes, and by chemical synthesis. See Abstract. Notably, Izumi never discusses or discloses non-GMO metal amino acid chelates.

C. Rejections Under 35 U.S.C. § 102(b)

1. Requirements for Prima Facie Anticipation

The Examiner has rejected at least a portion of claims 34-36, 41-45, and 50-53 under § 102(b) as being anticipated by Hsu, Ashmead '424 or Ashmead '427.

In order to establish a *prima facie* case of anticipation, the Examiner must show that each and every element is present in a single prior art reference. Specifically, the Appellants wish to briefly state what is required to sustain such a rejection according to the current case law. It is well settled that "[a] claim is anticipated only if each and every element as set forth in the claims is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil of California*, 814 F.2d 628, 2 U.S.P.Q. 2d 1051, 1053 (Fed. Cir. 1987). In order to establish anticipation under 35 U.S.C. 102, all elements of the claim must be found in a single reference. *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 231

U.S.P.Q. 81, 90 (Fed. Cir. 1986), *cert. denied* 107 S.Ct. 1606 (1987). In particular, as pointed out by the court in *W.L. Gore & Assoc., Inc. v. Garlock, Inc.*, 220 U.S.P.Q. 303, 313 (Fed. Cir. 1981), *cert denied*, 469 U.S. 851 (1984), "anticipation requires that each and every element of the claimed invention be disclosed in a prior art reference." "The identical invention must be shown in as complete detail as is contained in the...claim." *Richardson v. Suzuki Motor Co.* 9 U.S.P.Q. 2d 1913, 1920 (Fed. Cir. 1989).

With the above background in mind, Appellants contend that the Examiner has not met this burden with respect to any of the claims on appeal. Particularly, Appellants submit that the PTO has failed to show that each and every element of the claimed invention is contained in these references. Appellants now turn to a discussion of the specific rejections at issue.

2. Rejections to Claims 34-36, 41-45, and 50-53

The Examiner has rejected at least a portion of claims 34-36, 41-45, and 50-53 under § 102(b) as being anticipated by Hsu, Ashmead '424 or Ashmead '427. However, none of these references teach the presently recited method of producing a non-GMO metal amino acid chelate. As the Examiner has rejected both independent claims 34 and 43 under § 102, Appellants direct the following remarks to these claims, with the understanding that the following discussion is equally applicable to each claim depending from these independent claims.

Appellants submit that none of these references provide a method of preparing or administering a non-GMO metal amino acid chelate. In response to Appellants' arguments, the Examiner alleges "that there is nothing to suggest that the methods described in the cited references would direct one of ordinary skill in the art to

specifically choose a metal or amino acid from a genetically modified organism." See Final Office Action, dated January 24, 2008, page 9. Likewise, Appellants submit that there is nothing to suggest that the methods described in the cited references would direct one of ordinary skill in the art to specifically choose a metal or amino acid from a non-genetically modified organism. In fact, this lack of teaching is precisely the reason the methods of the present invention do not read on the prior art.

The Examiner further elaborates that "[w]ithout clear and convincing evidence, one of ordinary skill in the art would obtain a metal and an amino acid from what the applicant calls a 'non-GMO' source, which is inherent in the method." See Final Office Action, dated January 24, 2008, page 9. Appellants contend that the Examiner has misunderstood the claim. Both independent method claims require an affirmative non-GMO determination. The Examiner has alleged that since someone skilled in the art "would" obtain from a non-GMO source, the method is anticipated. Although Appellants do not agree that one skilled necessarily "would" obtain a non-GMO source, whether one could or would is immaterial since the present method claims recite an affirmative non-GMO determination. The fact that a non-GMO source could be used in the prior art does not implicitly or explicitly teach the recited element of an affirmative non-GMO determination. The Examiner has not shown this step anywhere in the prior art.

Additionally, the fact that all of the references cited in the present prosecution are silent as to the use of non-GMO compounds is significant. Even if, as the Examiner has intimated, one skilled in the art would use a non-GMO source, such a supposition does not negate making an affirmative non-GMO determination. In fact, if the sources are non-GMO, no determination would need to be made, which further supports patentability of the present method claims.

As previously argued, independent claims 34 and 43 specifically require an affirmative step of making a non-GMO determination for the metal and for the amino acid. Further, the final product must also be non-GMO, which according to the definition in the specification of non-GMO, is quite limiting. Relevant portions of the definitions from the specification are provided herein for the Board's convenience, as follows:

> The term "GMO" is an acronym for the term "genetically modified organism(s)."
> The term "GMO derivative" applies to any substance produced from, but not containing a genetically modified organism.
> The term "non-GMO" herein includes compositions that are not GMOs, and also are not derived from GMOs. In other words, non-GMO compositions are not genetically modified of themselves, and are prepared by processes other than those which include the use of genetically modified organisms. Thus, amino acid chelates prepared in accordance with embodiments of the present invention, such as for human, animal, or foliar application, must not include or be produced with the utilization of genetically modified organisms.

None of the references provided by the Examiner refer to any such affirmative step of determination as required by claims 34 and 43, and further, as the final product must also be non-GMO, there is no teaching or suggestion in any of the references that the chelates described therein unambiguously meet this criteria. As such, Appellants contend that the two independent method claims and subsequent dependent claims are clearly distinct over the cited references.

Appellants also wish to address the Examiner's inherency comment with respect to the present method claims. Specifically, the Examiner has argued that one skilled in the art would obtain a metal and amino acid from a non-GMO source, "which is inherent in the method." See Final Office Action, mailed January 24, 2008, page 9. As the Examiner is particularly relying on this doctrine, Appellants wish to provide the Board with applicable case law. Specifically, the Federal Circuit Court of

Appeals stated "[u]nder the doctrine of inherency, if an element is not expressly disclosed in a prior art reference, the reference will still be deemed to anticipate a subsequent claim if the missing element 'is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill' (citations omitted). Rosco, Inc. v. Mirror Lite Co., 304 F.3d 1373, 1380 (Fed. Cir. 2002). The Court further states that "'[i]nherent anticipation requires that the missing descriptive material is "necessarily present," not merely probably or possibly present, in the prior art'" (citations omitted). Id. As such, Appellants submit that the appropriate standard in establishing an anticipatory rejection through inherency has been well defined by the courts.

Appellants submit that the PTO has not established that a non-GMO determination is necessarily present in the presently cited references. Specifically, none of the references indicate that a non-GMO determination was made, needs to be made, or should be made. As such, Appellants submit that the Examiner's reliance on inherency is inappropriate and cannot serve to establish a proper 102 rejection.

Therefore, Appellants submit that the rejected claims under 102(e) are not anticipated by the cited references as each rejection does not teach each and every element of the presently claimed invention. As such, Appellants request the present rejections to these claims be overturned.

D. Rejections Under 35 U.S.C. § 103(a)

1. Requirements for Prima Facie obviousness

The Examiner has rejected claims 34, 37-40, 43, and 46-49 under § 103(a) as being *prima facie* obvious over Hsu in view of Izumi. The Patent and Trademark Office (PTO), through the Examiner, has the burden of establishing a *prima facie* case

of obviousness. *In re Fine*, 837 F.2d 1071, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1998). To satisfy this burden, the PTO must meet the criteria set out in M.P.E.P. § 706.02(j):

> [T]hree basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on applicant's disclosure. *In re Vaeck,* 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Moreover, the obviousness analysis must comply with the statutory scheme as explained by the Supreme Court in *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966), namely, consideration must be given to: (1) the scope and content of the prior art, (2) the differences between the prior art and the claimed invention, (3) the level of ordinary skill in the pertinent art, and (4) additional evidence, which may serve as indicia of non-obviousness.

An excellent summary of how the prior art must be considered to make a case of *prima facie* obviousness is contained in *In re Ehrreich et al.*, 220 U.S.P.Q. 504, 509-511 (CCPA 1979). There the court states that a reference must not be considered in a vacuum, but against the background of the other references of record. It is stated that the question of a § 103 case is what the reference(s) would "collectively suggest" to one of ordinary skill in the art. However, the court specifically cautioned that the Examiner must consider the entirety of the disclosure made by the reference and avoid combining them indiscriminately.

In finding that the "subject matter as a whole" would not have been obvious in *Ehrreich* the court concluded:

> "Thus, we are directed to no combination of prior art references which would have rendered the claimed subject matter as a

> whole obvious to one of ordinary skill in the art at the time the invention was made. The PTO has not shown the existence of all the claimed limitations in the prior art or any suggestion leading to their combination in the manner claimed by applicants." (underlining added)

It has been widely recognized that virtually every invention is a combination of elements and that most, if not all, of these will be found somewhere in an examination of the prior art. This reasoning lead the court, in *Connell v. Sears, Roebuck & Co.*, 220 U.S.P.Q. 193, 199 (Fed. Cir. 1983) to state:

> "...it is common to find elements or features somewhere in the prior art. Moreover, most if not all elements perform their ordained and expected function. The test is whether the claimed invention as a whole, in light of all the teachings of the references in their entireties, would have been obvious to one of ordinary skill in the art at the time the invention was made." (underlining added)

With the above background in mind, Appellants contend that the Examiner has not met this burden with respect to any of the claims on appeal. Particularly, Appellants submit that the PTO has failed to show that each and every element of the claimed invention is contained in the combined references. Appellants now turn to a discussion of the rejection at issue, and the references on which they are based.

2. The rejection of Claims 34, 37-40, 43, and 46-49

The Examiner has rejected claims 34, 37-40, 43, and 46-49 over Hsu in view of Izumi. However, according to M.P.E.P. § 706.02(j), to render a claim prima facie obvious, the asserted prior art reference (or references when combined) must teach or suggest all of the claim limitations. Appellants submit that the present combination asserted by the Examiner does not teach or suggest each and every element of the rejected claims. Appellants renew the previous arguments with respect to the Hsu

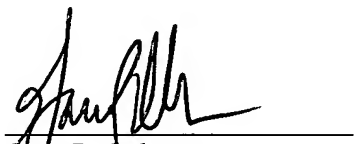
reference. Additionally, Appellants contend that the Examiner has failed to show any language in any reference in the current office action related to affirmative steps to select non-GMO materials for use in preparing the non-GMO chelates. As such, no combination of references cited by the Examiner teaches or suggests every element of the present method claims. The present combination, therefore, cannot support a *prima facie* case of obviousness. As such, Appellants request that the present rejection be overturned.

E. Conclusion

Appellants respectfully submit that the claims on appeal set forth in the Appendix are patentably distinct from the asserted prior art references. Particularly, none of the asserted combinations of references would teach one of ordinary skill in the art within the meaning of 35 U.S.C. § 102(b) or 35 U.S.C. § 103(a) to arrive at the presently claimed invention. Appellants contend that none of the cited references, alone or in combination, teach each and every element of the claimed invention, and that a *prima facie* case of anticipation or obviousness has not been established.

For at least these reasons, Appellants respectfully request that the Board of Appeals reverse the rejections and remand the case to the Examiner for allowance.

Dated this 6th day of June, 2008



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VIII. CLAIMS APPENDIX

1-33. (canceled).

34. (original) A method of preparing a non-GMO metal amino acid chelate, comprising:

a) selecting an amino acid source determined to be non-GMO;

b) selecting a metal source determined to be non-GMO; and

c) chelating an amino acid of the amino acid source to a metal of the metal source, thereby forming a non-GMO metal amino acid chelate.

35. (original) A method as in claim 34, wherein during the step of selecting the amino acid source, if a first amino acid source is a GMO, additional amino acid sources are evaluated until a non-GMO amino acid source is ascertained.

36. (original) A method as in claim 34, wherein during the step of selecting the metal source, if a first metal source is a GMO, additional metal sources are evaluated until a non-GMO metal source is ascertained.

37. (original) A method as in claim 34, wherein the naturally occurring amino acid used to prepare the amino acid chelates is prepared by a method other than protein hydrolysis.

38. (original) A method as in claim 37, wherein the naturally occurring amino acid used to prepare the amino acid chelates is prepared synthetically.

39. (previously presented) A method as in claim 37, wherein the naturally occurring amino acid used to prepare the amino acid chelates is prepared by fermentation.

40. (original) A method as in claim 34, wherein the naturally occurring amino acid used to prepare the amino acid chelates is prepared by protein hydrolysis, and wherein the protein used in the hydrolysis is non-GMO.

41. (original) A method as in claim 34, further comprising selecting an additive determined to be non-GMO, and including the additive as a mixture with the non-GMO metal amino acid chelate.

42. (original) A method as in claim 41, wherein the additive is selected from the group consisting of non-GMO organic acids, non-GMO free amino acids, non-GMO amino acid salts, non-GMO fillers, non-GMO flow control agents, non-GMO lubricants, non-GMO flow agents, non-GMO hydroscopicity minimizing agents, non-GMO pH control agents, non-GMO catalysts, non-GMO vitamins, non-GMO dust control agents, non-GMO binders, non-GMO disintegrating agents, non-GMO flavoring agents, non-GMO taste-reducing agents, non-GMO capsule shells, non-GMO shellacs, non-GMO waxes, non-GMO emulsifiers, non-GMO oils, and combinations thereof.

43. (original) A method of administering a metal amino acid chelate, comprising:

a) formulating a non-GMO metal amino acid chelate by:

i) selecting an amino acid source determined to be non-GMO,

ii) selecting a metal source determined to be non-GMO, and

iii) chelating an amino acid of the amino acid source to a metal of the metal source, thereby forming the non-GMO metal amino acid chelate; and

b) administering the non-GMO metal amino acid chelate to the subject.

44. (original) A method as in claim 43, wherein during the step of selecting the amino acid source, if a first amino acid source is a GMO, additional amino acid sources are evaluated until a non-GMO amino acid source is ascertained.

45. (original) A method as in claim 43, wherein during the step of selecting the metal source, if a first metal source is a GMO, additional metal sources are evaluated until a non-GMO metal source is ascertained.

46. (original) A method as in claim 43, wherein the naturally occurring amino acid used to prepare the amino acid chelates is prepared by a method other than protein hydrolysis.

47. (original) A method as in claim 46, wherein the naturally occurring amino acid used to prepare the amino acid chelates is prepared synthetically.

48. (previously presented) A method as in claim 46, wherein the naturally occurring amino acid used to prepare the amino acid chelates is prepared by fermentation.

49. (original) A method as in claim 43, wherein the naturally occurring amino acid used to prepare the amino acid chelates is prepared by protein hydrolysis, and wherein the protein used in the hydrolysis is non-GMO.

50. (original) A method as in claim 43, further comprising selecting an additive determined to be non-GMO, and including the additive as a mixture with the non-GMO metal amino acid chelate.

51. (original) A method as in claim 50, wherein the additive is selected from the group consisting of non-GMO organic acids, non-GMO free amino acids, non-GMO amino acid salts, non-GMO fillers, non-GMO flow control agents, non-GMO lubricants, non-GMO flow agents, non-GMO hydroscopicity minimizing agents, non-GMO pH control agents, non-GMO catalysts, non-GMO vitamins, non-GMO dust control agents, non-GMO binders, non-GMO disintegrating agents, non-GMO flavoring agents, non-GMO taste-reducing agents, non-GMO capsule shells, non-GMO shellacs, non-GMO waxes, non-GMO emulsifiers, non-GMO oils, and combinations thereof.

52. (previously presented) A method as in claim 34, wherein the non-GMO metal amino acid chelate has an amino acid to metal molar ratio from about 1:1 to 4:1.

53. (previously presented) A method as in claim 43, wherein the non-GMO metal amino acid chelate has an amino acid to metal molar ratio from about 1:1 to 4:1.

IX. EVIDENCE APPENDIX

(No matter presented)

X. RELATED PROCEEDINGS APPENDIX

(No matter presented)